



### REMARKS

Reconsideration of this application is respectfully requested. Currently, claims 19, 20, 30, 31 and 33 remain pending in the application.

#### Rejection under 35 U.S.C. § 102(e)

Claims 19, 20, 30, 31 and 33 were rejected under 35 U.S.C. § 102(e)<sup>1</sup> as allegedly being anticipated by U.S. Patent No. 6,274,149 (“the ’149 patent”). Applicants respectfully traverse this rejection.

The present invention relates to a method of providing an adjuvant effect to a vaccine comprising at least one antigen or at least one in vivo generator of a compound comprising an amino acid sequence, where the method comprises combining the antigen or in vivo generator with a mixture of surfactants having an overall HLB number of between 5 and 15, where the surfactants comprise ethoxylated derivatives of esters of fatty acids having 12-22 carbon atoms with sorbitan or mannitan having a number of EOs of between 1 and 60; or ethoxylated derivatives of oils having a number of EOs between 1 and 60. Importantly, it will be appreciated that, by virtue of the Election of Species Requirement, it is the polyethoxylated mannitan oleate which applicants have elected initially for prosecution on the merits. Specifically, applicant has elected **mannitan oleate with 8 EO units**.

In the restriction requirement of August 2, 2001 (paper no. 7), the office required an election of species to a “**specific** surfactant” [emphasis in original] if Group V was elected. In the response of October 2, 2001, Applicants elected Group V (claims 19-20 and 30-32) and the species of composition H (Mannitan oleate (**8 EOs**)) with traverse. In the office action of December 13, 2001 (paper no. 10), the office made the restriction requirement final. In the

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<sup>1</sup> As pointed out in the previous response, the claims are rejected under 35 U.S.C. §102(b). However, the Office has quoted 35 U.S.C. §102(e)(1). Since the instant application was filed on October 30, 2000 and U.S. Patent No. 6,274,149 has a publication date of August 14, 2001, it qualifies as prior art under 35 U.S.C. §102(e) and not 35 U.S.C. §102(b).

office action of July 7, 2003, paragraph 4, the office confirmed the position that the application had been examined **“only as it recites the chosen species of ‘composition h, mannitan oleate (8EOs).”** [Emphasis added]. Therefore, in order to reject the examined claims under 35 U.S.C. § 102(e), the office was required to demonstrate that the prior art teaches all of the required claim limitations including the limitation of **mannitan oleate that had been ethoxylated with 8 ethylene oxide units**. As explained below, the Office has failed to meet this burden.

“Anticipation under 35 U.S.C. § 102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention.” (*Electro Med. Sys. S.A. v. Cooper Life Sciences*, 32 U.S.P.Q.2d 1017, 1019 (Fed. Cir. 1994)). Applicants respectfully submit that the ‘149 patent does not define a method comprising the combination of a polyethoxylated mannitan oleate according to the claimed method. More specifically, it is respectfully submitted that the ‘149 patent does not teach the recited polyethoxylated mannitan oleate, specifically a polyethoxylated mannitan oleate with 8 EO’s.

The Office cites to the recitation of MONTANIDE in Table I for the disclosure of mannitan oleates and where mannitan oleate equals mannide oleate in the Chemical Abstracts Registry File. The Office then relies on column 4, lines 25, 48, and 53 as purportedly showing that the surfactants may be polyethoxylated, modified with ethylene oxide, or ethoxylated.

However, neither the ‘149 patent alone or in combination with the Chemical Abstract Registry File discloses the particular ethoxylated derivative of mannitan oleate. While the ‘149 patent teaches MONTANIDE, this particular compound is not ethoxylated. In addition, although the ‘149 patent discloses that the surfactants therein may be ethoxylated, it does not disclose the elected ethoxylated derivatives of mannitan oleate, **particularly where the ethoxylated mannitan oleate has an EO number of 8**.

Regarding the elected species, the Office has failed to identify the specific teaching in the ‘149 patent that sets forth the presence of 8 EO units. Paragraph 4 of the office action states that the “reference further teaches that the composition may be polyethoxylated (column 4, line 25), modified with ethylene oxide (column 4, line 48), or ethoxylated (column 4, line 53).” The office action then states that the reference “clearly anticipates” the claimed

invention. However, the office action fails to mention the EO number of 8, to which Applicants have been restricted. Indeed, Applicants urge that it is not possible for the '149 patent to clearly anticipate the invention being examined as this patent does not recite the elected limitation of an ethoxylated mannitan oleate, particularly an ethoxylated mannitan oleate containing an EO number of 8. Applicants note that even if not limited to the elected species of ethoxylated mannitan oleate with an EO number of 8, the present claims still would not be anticipated as the reference does not teach ethoxylated mannitan oleates.

The Chemical Abstract Registry File adds nothing to the '149 patent, because this reference merely describes unethoxylated derivatives of mannitan oleate and is only cited to equate mannitan oleates to mannide oleates. Therefore, the Office has not demonstrated every element of the claimed invention and, in particular, an ethoxylated mannitan oleate.

In view of the above remarks, Applicants respectfully submit that the '149 patent does not teach the limitations of claims 19, 20, 30, 31, and 33. Accordingly, Applicants respectfully request the Examiner to withdraw the § 102(e) rejection over the '149 patent.



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### CONCLUSION

Applicants respectfully request consideration of the above remarks. In view of the above remarks, early notification of a favorable consideration is respectfully requested.

Although no additional fees are believed due, the Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 50-0206.

Respectfully submitted,

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By:

Robert M. Schulman  
Registration No. 31,196

Jeffrey B. Robertson  
Registration No. 59,122

HUNTON & WILLIAMS LLP  
Intellectual Property Department  
1900 K Street, N.W.  
Suite 1200  
Washington, DC 20006-1109  
(202) 955-1500 (telephone)  
(202) 778-2201 (facsimile)  
RMS/JBR